DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

9188d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2002-DT-08

October 30, 2001

Mr. Duane R. Elliott
President
Emergent Innovations, LLC.
8202 North Kenwood Avenue
Indianapolis, IN 46260

Dear Mr. Elliott:

Investigator Bernard P. Heidt conducted an inspection of your firm dated August 6-17, 2001. At the conclusion of that inspection, Investigator Heidt issued to you a FORM FDA-483, list of Inspectional Observations, (copy attached).

The deviations from the Quality System Regulations, Title 21 Code of Federal Regulations (CFR) Part 820, listed on the FDA-483, cause your patient restraint, and other medical devices, to be adulterated within the meaning of Section 501(h) [21 U.S.C. 351(h)] of the Federal Food, Drug and Cosmetic Act (the Act). The deviation from the Medical Device Reporting Regulations, Title 21 CFR Part 807, cause your devices to be misbranded within the meaning of Section 502(t)(2) [21 U.S.C. 352(t)(2)] of the Act.

1. You failed to establish written procedures, as required by 21 CFR 820.22, for conducting audits of the quality assurance system, and you failed to have conducted any quality audits.

2. Your device master records fail to comply with the requirements of 21 CFR 820.181 in that:
   a. They lack a record of review and approval.
   b. They lack reference to component specifications.
   c. They lack reference to a device history record.
   d. They lack a description of the quality assurance procedures and specifications.
   e. There is no documentation of the approval of the specific completed protective restraint device, that is provided as part of the master record to the person or firm that sews together the fabric components.

3. You failed to establish and maintain device history records as required by 21 CFR 820.184, to include a record of the date of manufacture, the quantity manufactured, the quantity released for distribution, records of acceptance demonstrating conformance with the device master, documentation of labeling used, and any device identification or control numbers used.

4. You failed to establish and maintain procedures, as required by 21 CFR 820.30(a)-(j), to control the design of the patient restraint devices. Those who design medical devices must be aware of the design control requirements in the regulation and comply with them. Unsafe and ineffective devices are often the result of informal development that does not ensure the proper establishment and assessment of design requirements that are necessary to develop a medical device that is safe and effective for the intended use of the devices, and that meets the needs of the user. The intrinsic quality of devices, including their safety and effectiveness, is established during the design phase.

5. You failed to have in place a written plan, as required by 21 CFR 807, to evaluate complaints and other reports of product malfunctions.

We acknowledge receipt of your September 6, 2001 letter written in response to the FDA-483. Your letter fails to describe any specific corrections you have taken. There were no documents to demonstrate the type of corrections you may be preparing, and you failed to indicate a date when you expect to bring your firm into compliance with the regulations.

The above is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the regulations. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, pending 510(k) or PMA applications and export approval requests, may not be approved until the above violations are corrected.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice, such as seizure, injunction, or civil money penalties.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, as to the corrective action you have taken or intend to take, to bring your firm into compliance. If compliance cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely,

Joann M. Givens
District Director